REMARKS

The Final Office Action mailed May 28, 2008 has been received and carefully considered. Claims 1, 4, 6, 7, 9, 12-23, 25, 46-52, and 73-77 are now pending in the application. Claims 2, 3, 5, 8, 10-11, 24, 26-45, 53-72, and 78 have been canceled.
Claims 1, 4, 6, 7, 9, 12-15, 17-23, 25, 46-52, and 73-77 have been amended. Support for the claim amendments may be found throughout the specification, for example at [0034], [0039], [0040], [0042], [0043]. No new matter has been added.

Rejections under 35 U.S.C. § 102

On page 2 of the Final Office Action, the Examiner maintains the rejection of claims 1, 2, 4, 6, 7, 9, 12-23, 25, 46-52, and 73-77 under 35 U.S.C. § 102(b) "as being clearly anticipated by" U.S. Patent No. 4,014,322 to Shah. Applicants traverse the rejection.

More specifically, the Examiner asserts that Shah teaches 'an expandable collector member ... second collection size' because "figures 1-4 ... illustrate the absorbent sponge (56) having a first size (52) that is smaller than a second size after contact with the sample." Although the drawings in Shah may apparently indicate that the sponge has more than one side, the instant claimed invention is patentably distinct in both the structure and the function when compared to Shah, which states the following:

> Referring now to FIGS. 1-3, there is shown a sterile device generally designated 20 for collecting an aseptic sample or specimen of urine. The device 20 has a container 22 having a bottom 24 and a sidewall 26 defining a sterile chamber 28, and having an opening 30 at a top 32 of the container communicating with the chamber 28. The device has a ***lid 34 releasably attached to the top 32 of the container 22*** by cooperating threads 36, such that the lid 34 covers the container opening 30 and closes the chamber 28 when the lid is secured to the container
>
> Before wetting, the diameter of the bore 58 is preferably of a size less than the outside diameter of the shaft 40 adjacent the slot 52, while the thickness of the sponge 56 is preferably of a size approximately equal to the width of the slot 52, such that the unwetted sponge 56 is retained in position on the shaft 40 in the slot 52. When wetted, the sponge 56 expands both laterally and longitudinally relative the shaft 40, such that lateral expansion of the sponge 56 enlarges the bore 58 to a diameter size greater than the outside diameter of the shaft 40, thus permitting expansion of the sponge 56 longitudinally along the shaft 40, as shown in FIG. 3. ...
>
> The sponge 56 absorbs a sample from the midstream portion of the urine discharge while laterally and longitudinally expanding relative the shaft, as previously described.

Referring to FIG. 5, as the shaft 40 moves through the lid, the relatively small second slot 54 passes through the lid aperture 38, after which the first slot 52 receives ***the lid 34 and stops movement of the shaft*** at a second outer position of the shaft when the specimen has been substantially compressed from the sponge 56. The interengaged lid 34 and slot 52 subsequently retain the sponge in its compressed configuration intermediate the plate 50 and lid 34. As shown in FIG. 5, the handle 48 may be broken from the remainder of the shaft 40 at the second slot 54 which defines an area of weakness in the shaft 40. At this time, the aseptic sample has been collected in the lower part of the container chamber 28, and the handle 48 of the device has been removed to permit compact storage of the container and retained sample until ready for analysis when the lid 34 may be removed from the container 22 to pour the aseptic sample from the container.

The lid 34 may be removed from the container 22 while the sample receiving part of the device is held by the handle or outer portion 48 of the shaft 40. … After the midstream urine sample has been absorbed in the sponge 56, the inner end 42 of the shaft 40 may be positioned in the plate aperture, and the lid may be moved toward the top 32 of the container 22 and secured in place on the container. ***During this time, the wetted sponge 56 is compressed between the plate 50 and the lid 34 to release the aseptic sample from the sponge 56***. The sample passes from the sponge through the openings 76 to a lower part of the chamber 28 for collection. If desired, the lid 34 may be removed from the container 22, and the sample may be poured from the container for analysis.

FIG. 1

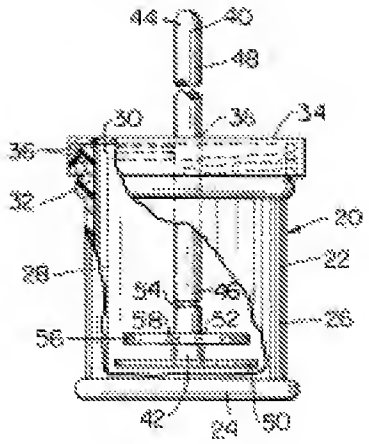
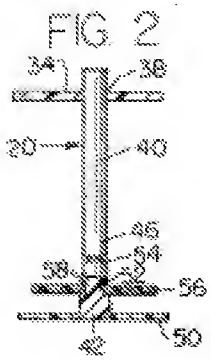


FIG. 2



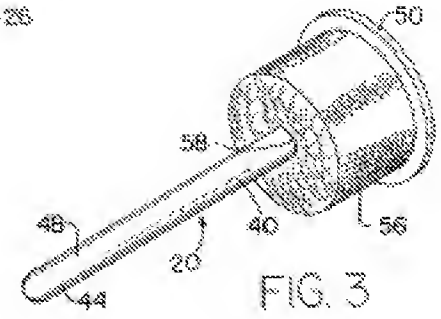


FIG. 3

FIG. 4

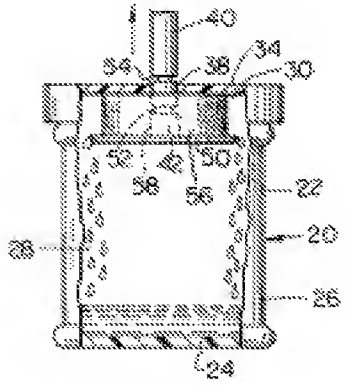
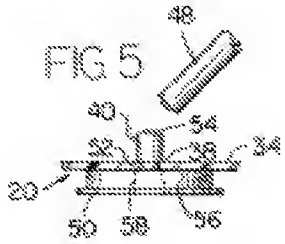


FIG. 5



These passages and figures clarify that there is no structure in the device of Shah that defines the size of the sponge - the size of the contracted or expanded sponge is determined solely by the sponge itself:

> After a relatively short period of time, such as five to ten seconds, the sponge 56 will have reached its enlarged configuration containing the specimen …

There is no structure in Shah by which the size of the sponge is defined by a configurable distance between the collector portion second end and the handle portion second end as in the instant claims. Additionally, there is no structure in or around the sponge in Shah that with the structure of the collector portion second end being movable relative to the handle portion: in Shah, the handle and the end holding the sponge remain fixed and unmovable.

Moreover, the structure of the claimed sample collecting device has a built-in gauge for when sufficient sample is obtained: a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size. This was not of concern in Shah, which clearly refers to collection of urine as shown by the passages provided above, as well as the following:

> A feature of the present invention is that the patient may utilize the handle means for placing the absorption means in the midstream portion of a urine discharge.
>
> Another feature of the present invention is that the absorption means receives and retains the midstream portion of the urine discharge.
>
> Yet another feature of the invention is that the device permits placement of the absorption means in the discharge without splashing of the discharge against the patient's hands.

It is well known in the art that urine is a plentiful sample. In contrast, the claimed invention may be used to obtain samples that are in limited quantity, such as saliva, where it is beneficial that the device itself can indicate when enough sample has been collected. Hence, in the claimed device when the sponge collection size reaches the collector portion extended size, sufficient sample has been collected for analysis.

Although Applicants remain firm that the limitations just discussed support the patentability of the claimed invention over Shah, Applicants have nevertheless amended claim 1 to further clarify the advantages of the claimed invention, in that the collector portion also includes structure (a blocking portion) that defines a sample retaining size of the collector portion and impedes movement of the collector portion to a size that is less than the sample retaining size, the sample retaining size being formed when the blocking portion engages with the handle portion second end, such that said blocking portion allows the discharge of a first portion of sample for assay from said sponge while retaining a second portion of sample in said sponge for subsequent assay. There is simply no equivalent structure or function in Shah that defines the amount of sample expressed from the sponge such that the sponge retains an amount

of sample defined as the retained sample size. Instead, the container of Shah holds all the sample:

> At this time, the aseptic sample has been collected in the lower part of the container chamber 28, and the handle 48 of the device has been removed to permit compact storage of the container and retained sample until ready for analsis when the lid 34 may be removed from the container 22 to pour the aseptic sample from the container.
>
> When it is desired to obtain the sample from the container chamber, the cap 88 may be removed from the extension 84, and a pipet may be passed through the port 86 to withdraw the sample from the lower part of the container chamber.

The Examiner states that "figures 1-4 ... illustrate the absorbent sponge(56) having a first size(52) that is smaller than a second size after collection with the sample." The structure (52), however, does not refer to the size of the sponge, but refers to a "slot":

> The device has a circular compression plate 50 attached to the shaft 40 adjacent its inner end 42, such that the plate 50 extends outwardly from the shaft 40. The shaft 40 has ***a first slot 52*** extendng peripherally around the shaft 40 at a location slightly spaced from the plate 50 toward the outer end 44 of the shaft 40. In a preferred form, the width of the ***slot 52*** is approximately equal to or slightly greater than the thickness of the lid 34 for a purpose which will be described below. The shaft 40 also has a second slot 54 extending peripherally around the shaft 40 and spaced slightly from the ***first slot 52*** toward the outer end 44 of the shaft 40. The width of the second slot 54 is less than the thickness of the lid 34 adjacent the aperture 38.

Regarding the sponge, there is no description of it having a second collection size and a sample retaining size defined by structure in the collector portion:

> In a suitable example, the sponge 56 may have a thickness or length of approximately 1/8 inch (.32 cm.) before wetting, and an enlarged or expanded length approximately equal to 1 inch (2.54 cm.) when wetted. Such a sponge may contain up to twenty cubic centimeters of liquid when saturated.

Perhaps the Examiner assumes that the drawing in Fig. 4 somehow shows the sponge at an intermediate but fixed size. It does not, but releases all of the sample:

> With reference to FIG. 4, *after the lid 34 has been secured to the* ***container*** 22, the shaft 40 may be moved outwardly through the lid aperture 38 to reduce the spacing between the plate and lid, such that the wetted sponge 56 is compressed between the plate 50 and the lid 34 to ***release the sample*** in an aseptic manner into a lower part of the container chamber 28. Referring to FIG. 5, as the shaft 40 moves through the lid, the relatively small second slot 54 passes through the lid aperture 38, after which the first slot 52 receives the lid 34 and stops movement of the shaft at a second outer position of the shaft *when the specimen has been substantially compressed from the sponge 56*. The interengaged lid 34 and slot 52

subsequently retain the sponge in its compressed configuration intermediate the plate 50 and lid 34.

Anticipation under 35 U.S.C. § 102 requires that a single prior art reference disclose each and every limitation of the claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sci.*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). "[F]or anticipation under 35 U.S.C. § 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." MPEP 706.02(IV). It is clear from the foregoing discussion that Shah does not support this § 102 rejection because there are numerous structures in the claimed invention that are simply absent in Shah, hence Applicants respectfully request its withdrawal.

Rejections under 35 U.S.C. § 103

On pages 2-3 of the Final Office Action, the Examiner rejects claim 77 under 35 U.S.C. § 103(a) "as being unpatentable over Shah". Applicants traverse the rejection.

The Examiner maintains that "the choice of a perforated disk as a result effective variable that has the well known and predictable results..." It should be clear from the discussion above that much more than a perforated disk separates the instant claimed invention from that of Shah, and that Shah never contemplates. For example, Shah does not suggest:

a collector portion, attached to the handle, the end of which is movable relative to the handle;

the collector portion itself having three important and distinct sizes: an extended size, a contracted size, and a sample retaining size;

when enough sample has been adsorbed by the sponge such that it reaches the extended size of the collector portion, there is sufficient sample for assay;

when sample is expressed from the sponge in the collector portion, the collector portion retracts in relation to the handle;

the collector portion also includes structure (a blocking portion) that impedes retraction of the collector portion relative to the handle at a sample retaining size, such that the blocking portion regulates the discharge of a first portion of sample for assay from the sponge while retaining a second portion of sample sponge for subsequent assay.

Each of these features is represented by a limitation in claim 1, and is not suggested in

Shah. Hence, Shah does not support a § 103 rejection, and Applicants respectfully request that the rejection of claim 77 be withdrawn.

CONCLUSION

In view of the foregoing, the present application is now believed to be in condition for allowance. Should the Examiner find some issue to remain unresolved, however, or should any new issues arise that could be resolved through discussions with Applicants' representative, then the Examiner is invited to telephone the undersigned to expedite further prosecution of this application.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 19-2380. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

Date: August 28, 2008

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